



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/089,894	06/03/1998	ARKADY L. BOMSHEYN	19603/871(CR)	3314

7590

02/06/2002

MICHAEL L. Goldman
Nixon Peabody LLP
Clinton Square, P.O. Box 31051
Rochester, NY 14603

EXAMINER

LUKTON, DAVID

ART UNIT

PAPER NUMBER

1653

DATE MAILED: 02/06/2002

20

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/089,894

Applicant(s)

Bomshyeyn

Examiner

David Lukton

Art Unit

1653



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on Jan 15, 2002

2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-47 is/are pending in the application

4a) Of the above, claim(s) _____ is/are withdrawn from consideration

5) ☒ Claim(s) 1 and 2 is/are allowed.

6) ☒ Claim(s) 3-47 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirements

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

19) ☐ Notice of Informal Patent Application (PTO-152)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

20) ☐ Other: _____

Pursuant to the directives of paper No. 19 (filed 1/15/02), claims 3, 7, 10, 11, 14, 16, 17, 19, 21-23, 26, 28-36, 38, 39, 41, 45, 46 have been amended. Claims 1-47 remain pending.

Applicants' arguments filed 1/15/02 have been considered and found persuasive in part.

*

Claims 3-47 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Claim 3 is indefinite because of its failure to recite that the time period of reaction is sufficient to form the target diether. The following format is suggested (the designations "formula II" and "formula III" have been created here):

A method of synthesizing a diether of formula II
{structure as recited}
wherein R is alkyl,

said method comprising

(a) reacting a di-alcohol of formula III with a nitrile of formula $RC \equiv N$ for a time and under conditions effective to form the diether of formula II, and

(b) isolating the diether of formula II.

- Claim 7 is indefinite because of its failure to recite that the time period of reaction is sufficient to form the target betulonic aldehyde. The following is suggested:

A method of preparing betulonic aldehyde comprising

(a) reacting betulinol with chromium anhydride in acetone in the presence of sulfuric acid for a time and under conditions effective to produce betulonic aldehyde, and

(b) isolating the betulonic aldehyde.

- Claim 10 is indefinite because it implies that “cooling” is equivalent to “oxidizing” and that adding water to a reaction mixture is equivalent to oxidizing. However, neither is true. In addition, claim 10 requires process steps that are not required of claim 7. The following is suggested for claim 10:

A method of preparing betulonic aldehyde comprising

(a) reacting betulinol with chromium anhydride in acetone in the presence of sulfuric acid for a time and under conditions effective to produce a reaction mixture that contains betulonic aldehyde;

(b) cooling the reaction mixture of step (a), and adding water to the reaction mixture, thereby forming a sediment containing the betulonic aldehyde; and

(c) isolating the betulonic aldehyde.

- Claim 11 is rendered indefinite because it requires process steps that are not required of claim 10, and because it is not clear what the relationship is between the isolation step of claim 7, and the recrystallization step of claim 11. The following is suggested:

A method of preparing betulonic aldehyde comprising

(a) reacting betulinol with chromium anhydride in acetone in the presence of sulfuric acid for a time and under conditions effective to produce a reaction mixture that contains betulonic aldehyde;

(b) cooling the reaction mixture of step (a), and adding water to the reaction mixture, thereby forming a sediment containing the betulonic aldehyde;

(c) crystallizing the betulonic aldehyde from the sediment of step (b); and

(d) isolating the betulonic aldehyde of step (c).

- Claim 17 is rendered indefinite because it fails to recite that the time period of reaction is sufficient to form the target conjugate. It is suggested that the claim be amended to recite that the reaction is carried out *for a time and under conditions effective to produce the betulinol-antibody conjugate.*
- Claim 22 is rendered indefinite because it fails to recite that the time period of reaction is sufficient to form the target betulinol peptide. It is suggested that the claim be amended to recite that the reaction is carried out *for a time and under conditions effective to produce the betulinol peptide.*
- Claim 23 is rendered indefinite because it fails to recite that the time period of reaction is sufficient to form the target conjugate. It is suggested that the claim be amended to recite that the reaction is carried out *for a time and under conditions effective to produce the betulinol-antibody conjugate.*
- Claim 29 is rendered indefinite because it fails to recite that the time period of reaction is sufficient to form the target haloacetylhydrazide. It is suggested that the claim be amended to recite that the reaction is carried out *for a time and under conditions effective to produce the haloacetylhydrazide.*
- Claim 30 is rendered indefinite because it fails to recite that the time period of reaction is sufficient to form the target hydrazide. It is suggested that the claim be amended to recite that the reaction is carried out *for a time and under conditions effective to produce the hydrazide.*
- Claim 31 is rendered indefinite because it fails to recite that the time period of reaction is sufficient to form the target betulinol peptide. It is suggested that the claim be amended to recite that the reaction is carried out *for a time and under conditions effective to produce the betulinol peptide.*

- Claim 33 is rendered indefinite because it fails to recite that the time period of reaction is sufficient to form the target betulinol/antibody conjugate. It is suggested that the claim be amended to recite that the reaction is carried out *for a time and under conditions effective to produce the betulinol-antibody conjugate*.
- Claim 34 requires process steps that are not required of claim 33. Claim 33 implies that the three ingredients (carrier, hydrazide, antibody) are combined together in one reaction. Claim 34, on the other hand, mandates a sequential process; claim 34 is not clearly subgeneric to claim 33. Accordingly, claim 34 should be written in independent form. Similarly, claim 35 should be written in independent form.
- Claim 36 recites a formula that contains the word "spacer". Since this is a substituent variable, some description of it should be provided. Similarly, some description of this variable should be present in claim 41. The description of claim 36 should take into account the possibility of having reactive groups present in the final product; such reactive groups are required by claims 38 and 39. Moreover, it appears that the "spacer" of claim 36 is different from the "spacer" of claim 41. In claim 41, the implication is that the reactive groups (e.g., hydroxysuccinimide) are present in order to achieve coupling between the antibody, and the "A" group. In claim 36, on the other hand, the implication is that in the final product, i.e., "HO-antibody-spacer (A)_n" reactive groups are present. The presence of such reactive groups in the final product, in fact, is mandated by claims 38 and 39. Thus, if this is intended, and not merely an oversight, it would appear that the term "spacer" should be defined differently in claims 36 and 41. On the other hand, if claim 36 does not require the presence of reactive groups, then claims 38-39 should be amended to reflect this.
- Claim 41 is rendered indefinite because it fails to recite that the time period of reaction is sufficient to form the target betulinol/antibody conjugate. It is suggested that the claim be amended to recite that the reaction is carried out *for a time and under conditions effective to produce the betulinol-antibody conjugate*.

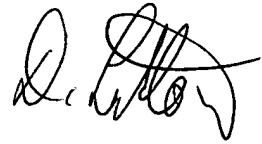
Serial No. 09/089,894
Art Unit 1653

-6-

*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton. Phone: (703) 308-3213.

An inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



**DAVID LUKTON
PATENT EXAMINER
GROUP 1800**